IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PFIZER INC., WYETH LLC, PFIZER PHARMACEUTICALS LLC, PF PRISM C.V. and PFIZER MANUFACTURING HOLDINGS LLC,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
ACCORD HEALTHCARE, INC., ACCORD HEALTHCARE LTD., and INTAS PHARMACEUTICALS LTD.,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Pfizer Inc., Wyeth LLC, Pfizer Pharmaceuticals LLC, PF PRISM C.V., and Pfizer Manufacturing Holdings LLC, (collectively "Pfizer"), by their attorneys, hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, that arises out of the submission by defendant Accord Healthcare, Inc. ("Accord Inc."), Accord Healthcare Ltd. ("Accord Ltd."), and Intas Pharmaceuticals, Ltd. ("Intas") (collectively "Defendants") of New Drug Application ("NDA") No. 208744 to the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell a generic version of Pfizer's TYGACIL® tigecycline injectable IV infusion, ("TYGACIL®") prior to the expiration of U.S. Patent No. 7,879,828 ("the '828 patent"), U.S. Patent No. 8,372,995 ("the '995 patent"), and U.S. Patent No. 8,975,242 ("the '242 patent").

PARTIES

2. Plaintiff Pfizer Inc. is a corporation organized and existing under the laws of the State of Delaware and having a place of business at 235 East 42nd Street, New York, New York 10017.

3. Plaintiff Wyeth LLC is a limited liability company organized and existing under the laws of the State of Delaware and having a place of business at 235 East 42nd Street, New York, New York 10017. Wyeth LLC's sole member is Pfizer Inc.

4. Plaintiff Pfizer Pharmaceuticals LLC is a limited liability company organized and existing under the laws of the State of Delaware and having a place of business at Bo. Carmelitas, Road 689, Km 1.9, Vega Baja, Puerto Rico 00693. Pfizer Pharmaceuticals LLC is a wholly-owned subsidiary of PF PRISM C.V.

5. Plaintiff PF PRISM C.V. is a limited partnership (*commanditaire vennootschap*) organized under the laws of the Netherlands, having its registered seat in Rotterdam, the Netherlands, and registered at the Trade Register held by the Chamber of Commerce in Rotterdam, the Netherlands, under number 51840456 and that for all purposes is represented by and acting through its general partner Pfizer Manufacturing Holdings LLC, a limited liability company organized under the laws of the State of Delaware, and having its address at 235 East 42nd Street, New York, New York 10017, registered in the register held by the Secretary of State of the State of Delaware under number 4869755. PF PRISM C.V. is the holder of NDA No. 21821, which has been approved by the FDA.

6. Plaintiff Pfizer Manufacturing Holdings LLC is a limited liability company organized and existing under the laws of the State of Delaware and having a place of business at

235 East 42nd Street, New York, New York 10017. Pfizer Manufacturing Holdings LLC is a general partner of PF PRISM C.V.

7. Upon information and belief, defendant Accord Inc. is a corporation organized and existing under the laws of the State of North Carolina, having a place of business at 1009 Slater Rd., Suite 210B, Durham, North Carolina 27703. Upon information and belief Accord Inc. is a wholly-owned subsidiary of Intas.

8. Upon information and belief, defendant Accord Ltd. is a corporation organized and existing under the laws of India, having a place of business at 2nd Floor, Chinubhai Centre, Off. Nehru Bridge, Ashram Road, Ahmedabad, India - 380 009. Upon information and belief Accord Ltd. is a wholly-owned subsidiary of Intas.

9. Upon information and belief, defendant Intas is a corporation organized and existing under the laws of India, having a place of business at 2nd Floor, Chinubhai Centre, Off. Nehru Bridge, Ashram Road, Ahmedabad, India - 380 009.

10. Upon information and belief, Accord Inc.'s preparation and submission of NDA No. 208744 was done at the direction, under the control, and for the direct benefit of Intas and/or Accord Ltd. Upon information and belief, Intas and/or Accord Ltd. directed Accord Inc. to submit NDA No. 208744.

11. Upon information and belief, and consistent with their practice with respect to other generic products, following any FDA approval of NDA No. 208744, Defendants will act in concert to distribute and sell the generic product described in NDA No. 208744 throughout the United States and within Delaware.

JURISDICTION AND VENUE

12. Jurisdiction and venue are proper in this District pursuant to 28 U.S.C. §§ 1331, 1338(a), 1391, 1400(b), and 2201.

13. Defendants are subject to personal jurisdiction in Delaware because, among other things, they regularly transact and/or solicit business in Delaware and have purposefully availed themselves of this forum such that they should reasonably anticipate being haled into court here.

14. Upon information and belief, Defendants together are in the business of selling drug products, which Defendants import or manufacture, distribute, sell, or offer to sell throughout the United States, including in Delaware; they derive substantial revenue from services or things used or consumed in Delaware; as part of their ordinary business practice of engaging in U.S. patent litigation, they have regularly and routinely litigated NDA and ANDA cases without contesting jurisdiction in this judicial district; they have, directly or through an agent, filed an NDA, and/or been actively involved in the preparation and submission of an NDA, for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the generic product described in NDA No. 208744 in the United States, including in Delaware; upon receiving FDA approval, they intend to offer to sell and sell the generic product described in NDA No. 208744 in the United States, including in Delaware, and thereby cause Pfizer to lose sales in Delaware; and by offering to sell or selling the generic product described in NDA No. 208744, Defendants would infringe a patent or patents owned by Pfizer, a Delaware corporation, and therefore would harm Pfizer in Delaware.

15. Upon information and belief, Defendants regularly do business in Delaware and have engaged in a persistent course of conduct within Delaware by continuously and systematically placing goods into the stream of commerce for distribution throughout the United

States, including Delaware, and/or by directly selling pharmaceutical products in Delaware. Defendants have done so with each other's authorization, participation, or assistance, or acting in concert with each other.

16. Upon information and belief, Intas, Accord Inc., and Accord Ltd. operate as an integrated, unitary generic pharmaceutical business. For example, Intas identifies Accord Inc. as the USA branch of its international operations on its website; Intas also identifies Accord Ltd. as the sole "Key Subsidiary" on its website, describing it as the "the offshore identity of Intas" and "marketing arm of Intas;" Intas includes Accord Inc. and Accord Ltd. in the Annual Report, published on its website, identifying both as subsidiaries; Intas, Accord Inc., and Accord Ltd. have overlapping officers and directors; and according to a Draft Red Herring Prospectus for Intas, dated June 14, 2013, references to "we" or "us" or "our" refer to "Our Company, and where the context requires, our Company, our Subsidiaries and other entities which are consolidated in the financial statements of our Company," (available at: http://www.sebi.gov.in/cms/sebi_data/attachdocs/1371534868962.pdf). The Intas website identifies http://www.accord-healthcare.com/ as the website for Accord Ltd. The Accord Ltd. website lists Accord Inc. as the sole contact information for the United States.

17. Upon information and belief, according to the Intas Prospectus: "We are a leading, *vertically integrated* Indian pharmaceutical company with global operations, engaged in the development, manufacture and marketing of pharmaceutical formulations. . . . Our products are marketed in over 60 countries, either *directly, through our subsidiaries* or indirectly, through supply, distribution and other arrangements with various leading global pharmaceutical companies. . . . Europe and the *United States* are currently our largest markets and key growth

drivers. . . . [W]e commenced operations [in the United States] in 2007." Intas Prospectus at 48 (emphasis added). The Intas website states that Accord Inc. has been in operation since 2007.

18. By offering to sell or selling the generic product described in NDA No. 208744, Defendants would infringe a patent or patents owned by Pfizer, a Delaware corporation.

19. By letter dated December 31, 2015, Defendants notified Pfizer pursuant to the Federal Food, Drug, and Cosmetic Act ("FDCA") that they had filed NDA No. 208744 (the "Notice Letter"). By sending its Notice Letter to Pfizer, a Delaware corporation, Defendants purposefully directed their activities at Pfizer in Delaware and therefore the consequences of its activities are suffered by Pfizer in Delaware.

20. Upon information and belief, Accord Inc. and Intas have availed themselves of the legal protections of the state of Delaware by filing counterclaims affirmatively seeking relief in other prior actions in this Court. *See, e.g.*, *Forest Laboratories LLC, et al. v. Accord Healthcare Inc.*, C.A. No. 15-272 (D. Del.); *Cephalon Inc. v. Accord Healthcare Inc., et al.*, C.A. No. 15-178 (D. Del.); *Acorda Therapeutics Inc. v. Accord Healthcare Inc. and Intas Pharmaceuticals Limited*, C.A. No. 14-932 (D. Del.); *Cephalon Inc. v. Accord Healthcare Inc. and Intas Pharmaceuticals Limited*, C.A. No. 13-2095 (D. Del.); *UCB Inc., et al. v. Accord Healthcare Inc. and Intas Pharmaceuticals Limited*, C.A. No. 13-1206 (D. Del.); *Pfizer Inc. and UCB Pharma GmbH v. Accord Healthcare Inc.*, C.A. No. 13-1155 (D. Del.); *Millennium Pharmaceuticals Inc. v. Accord Healthcare Inc., et al.*, C.A. No. 12-1490 (D. Del.); *Pfizer Inc., et al. v. Accord Healthcare Inc., et al.*, C.A. No. 11-1253 (D. Del.); *Aventis Pharma S.A. and Sanofi-Aventis US LLC v. Accord Healthcare Inc.*, C.A. No. 11-18 (D. Del.).

BACKGROUND

21. TYGACIL® is a tetracycline class antibacterial indicated for the treatment of complicated skin and skin structure infections, complicated intra-abdominal infections, and community-acquired bacterial pneumonia, in adults. Each TYGACIL® vial contains 50 mg tigecycline lyophilized powder for reconstitution for intravenous infusion and 100 mg of lactose monohydrate.

22. The ’828 patent, entitled “Tigecycline Compositions and Methods of Preparation” (Exhibit A hereto), was duly and legally issued on February 1, 2011 to Wyeth LLC, as assignee, and subject to the exclusive license referenced herein. TYGACIL® and the use thereof are covered by one or more claims of the ’828 patent, which has been listed in connection with TYGACIL® in the FDA’s publication Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the “Orange Book.”

23. The ’995 patent, entitled “Crystalline Solid Forms of Tigecycline and Methods of Preparing Same” (Exhibit B hereto), was duly and legally issued on February 12, 2013 to Wyeth LLC, as assignee, and subject to the exclusive license referenced herein. TYGACIL® and the use thereof are covered by one or more claims of the ’995 patent, which has been listed in connection with TYGACIL® in the Orange Book.

24. The ’242 patent, entitled “Tigecycline Compositions and Methods of Preparation” (Exhibit C hereto), was duly and legally issued on March 10, 2015 to Wyeth LLC, as assignee, and subject to the exclusive license referenced herein. TYGACIL® and the use thereof are covered by one or more claims of the ’242 patent, which has been listed in connection with TYGACIL® in the Orange Book.

25. In 2011, PF PRISM C.V. took an exclusive license to the '828 patent, patent application no. 11/440,032 (which later issued as the '995 patent), and all continuations of existing patents and patent applications relating to TYGACIL® (which includes the application that issued as the '242 patent). Thereafter, PF PRISM C.V. contributed its rights under the exclusive license to Pfizer Pharmaceuticals LLC.

26. Pfizer has all right, title, and interest in the '828 patent, the '995 patent, and the '242 patent, including the right to sue for infringement thereof.

27. Defendants notified Pfizer in the Notice Letter that they had submitted to the FDA NDA No. 208744 for a tigecycline injectable product for IV infusion containing 50 mg tigecycline ("Defendants' NDA Product"). Defendants' NDA Product is a drug product that is a generic version of TYGACIL®.

28. The purpose of Defendants' submission of NDA No. 208744 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Defendants' NDA Product prior to the expiration of the '828 patent, the '995 patent, and the '242 patent.

29. In the Notice Letter, Defendants also notified Pfizer that, as part of their NDA No. 208744, Defendants had filed certifications of the type described in Section 505(b)(2)(A)(iv) of the FDCA, with respect to the '828 patent, the '995 patent, and the '242 patent. Upon information and belief, Defendants submitted NDA No. 208744 to the FDA containing a certification pursuant to 21 U.S.C. § 355(b)(2)(A)(iv) asserting that the '828 patent, the '995 patent, and the '242 patent will not be infringed by the manufacture, use, offer for sale, sale, or importation of Defendants' NDA Product, or alternatively, that these patents are invalid.

30. In an exchange of correspondence, counsel for Defendants and counsel for Pfizer discussed the terms of Pfizer's Request for Confidential Access.

31. The parties, while reserving all rights, ultimately negotiated terms under which Pfizer could review NDA No. 208744, certain portions of the Drug Master File referenced therein, and a limited set of samples. But Defendants refused to produce other documents, data, and samples relevant to infringement, and offered to produce certain samples so close to the expiration of the forty-five day notice period that Defendants were deprived of adequate time to test and evaluate such samples.

32. This action is being commenced before the expiration of forty-five days from the date of the receipt of the Notice Letter.

COUNT I – INFRINGEMENT OF U.S. PATENT NO. 7,879,828 UNDER 35 U.S.C. § 271(e)(2)

33. Pfizer incorporates each of the preceding paragraphs 1–32 as if fully set forth herein.

34. Defendants' submission of NDA No. 208744 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Defendants' NDA Product prior to the expiration of the '828 patent was an act of infringement of the '828 patent under 35 U.S.C. § 271(e)(2)(A).

35. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Defendants' NDA Product would infringe one or more claims of the '828 patent, either literally or under the doctrine of equivalents.

36. Upon information and belief, Defendants will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Defendants' NDA Product with its proposed labeling upon approval of NDA No. 208744.

37. Upon information and belief, the use of Defendants' NDA Product in accordance with and as directed by Defendant's proposed labeling for that product would infringe one or more claims of the '828 patent.

38. Upon information and belief, Defendants plan and intend to, and will, actively induce infringement of the '828 patent when NDA No. 208744 is approved, and plan and intend to, and will, do so after approval.

39. Upon information and belief, Defendants know that their NDA Product and its proposed labeling are especially made or adapted for use in infringing the '828 patent, and that its NDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Defendants plan and intend to, and will, contribute to infringement of the '828 patent after approval of NDA No. 208744.

40. Upon information and belief, after approval of NDA No. 208744, Defendants will, without authority, import into the United States and/or offer to sell, sell, and/or use within the United States, a product which is made by a process that infringes one or more claims of the '828 patent prior to the expiration of the patent.

41. The foregoing actions by Defendants constitute and/or will constitute infringement of the '828 patent, active inducement of infringement of the '828 patent, and contribution to the infringement by others of the '828 patent.

42. Upon information and belief, Defendants have acted with full knowledge of the '828 patent and without a reasonable basis for believing that they would not be liable for infringing the '828 patent, actively inducing infringement of the '828 patent, and contributing to the infringement by others of the '828 patent.

43. Unless Defendants are enjoined from infringing the ’828 patent, actively inducing infringement of the ’828 patent, and contributing to the infringement by others of the ’828 patent, Pfizer will suffer irreparable injury. Pfizer has no adequate remedy at law.

COUNT II – INFRINGEMENT OF U.S. PATENT NO. 8,372,995 UNDER 35 U.S.C. § 271(e)(2)

44. Pfizer incorporates each of the preceding paragraphs 1–43 as if fully set forth herein.

45. Defendants’ submission of NDA No. 208744 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Defendants’ NDA Product prior to the expiration of the ’995 patent was an act of infringement of the ’995 patent under 35 U.S.C. § 271(e)(2)(A).

46. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Defendants’ NDA Product would infringe one or more claims of the ’995 patent, either literally or under the doctrine of equivalents.

47. Upon information and belief, Defendants will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Defendants’ NDA Product with its proposed labeling upon approval of NDA No. 208744.

48. Upon information and belief, the use of Defendants’ NDA Product in accordance with and as directed by Defendants’ proposed labeling for that product would infringe one or more claims of the ’995 patent.

49. Upon information and belief, Defendants plan and intend to, and will, actively induce infringement of the ’995 patent when NDA No. 208744 is approved, and plan and intend to, and will, do so after approval.

50. Upon information and belief, Defendants know that their NDA Product and its proposed labeling are especially made or adapted for use in infringing the ’995 patent, and that its NDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Defendants plan and intend to, and will, contribute to infringement of the ’995 patent after approval of NDA No. 208744.

51. Upon information and belief, after approval of NDA No. 208744, Defendants will, without authority, import into the United States and/or offer to sell, sell, and/or use within the United States, a product which is made by a process that infringes one or more claims of the ’995 patent prior to the expiration of the patent.

52. The foregoing actions by Defendants constitute and/or will constitute infringement of the ’995 patent, active inducement of infringement of the ’995 patent, and contribution to the infringement by others of the ’995 patent.

53. Upon information and belief, Defendants have acted with full knowledge of the ’995 patent and without a reasonable basis for believing that it would not be liable for infringing the ’995 patent, actively inducing infringement of the ’995 patent, and contributing to the infringement by others of the ’995 patent.

54. Unless Defendants are enjoined from infringing the ’995 patent, actively inducing infringement of the ’995 patent, and contributing to the infringement by others of the ’995 patent, Pfizer will suffer irreparable injury. Pfizer has no adequate remedy at law.

COUNT III – INFRINGEMENT OF U.S. PATENT NO. 8,975,242 UNDER 35 U.S.C. § 271(e)(2)

55. Pfizer incorporates each of the preceding paragraphs 1–54 as if fully set forth herein.

56. Defendants' submission of NDA No. 208744 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Defendants' NDA Product prior to the expiration of the '242 patent was an act of infringement of the '242 patent under 35 U.S.C. § 271(e)(2)(A).

57. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Defendants' NDA Product would infringe one or more claims of the '242 patent, either literally or under the doctrine of equivalents.

58. Upon information and belief, Defendants will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Defendants' NDA Product with its proposed labeling upon approval of NDA No. 208744.

59. Upon information and belief, the use of Defendants' NDA Product in accordance with and as directed by Defendants' proposed labeling for that product would infringe one or more claims of the '242 patent.

60. Upon information and belief, Defendants plan and intend to, and will, actively induce infringement of the '242 patent when NDA No. 208744 is approved, and plan and intend to, and will, do so after approval.

61. Upon information and belief, Defendants know that their NDA Product and its proposed labeling are especially made or adapted for use in infringing the '242 patent, and that its NDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Defendants plan and intend to, and will, contribute to infringement of the '242 patent after approval of NDA No. 208744.

62. Upon information and belief, after approval of NDA No. 208744, Defendants will, without authority, import into the United States and/or offer to sell, sell, and/or use within

the United States, a product which is made by a process that infringes one or more claims of the ’242 patent prior to the expiration of the patent.

63. The foregoing actions by Defendants constitute and/or will constitute infringement of the ’242 patent, active inducement of infringement of the ’242 patent, and contribution to the infringement by others of the ’242 patent.

64. Upon information and belief, Defendants have acted with full knowledge of the ’242 patent and without a reasonable basis for believing that they would not be liable for infringing the ’242 patent, actively inducing infringement of the ’242 patent, and contributing to the infringement by others of the ’242 patent.

65. Unless Defendants are enjoined from infringing the ’242 patent, actively inducing infringement of the ’242 patent, and contributing to the infringement by others of the ’242 patent, Pfizer will suffer irreparable injury. Pfizer has no adequate remedy at law.

COUNT IV – DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 7,879,828

66. Pfizer incorporates each of the preceding paragraphs 1–65 as if fully set forth herein.

67. Defendants have knowledge of the ’828 patent.

68. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Defendants’ NDA Product would infringe one or more claims of the ’828 patent, either literally or under the doctrine of equivalents.

69. Upon information and belief, Defendants will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Defendants’ NDA Product with its proposed labeling after approval of NDA No. 208744.

70. Upon information and belief, the use of Defendants' NDA Product in accordance with and as directed by Defendants' proposed labeling for that product would infringe one or more claims of the '828 patent.

71. Upon information and belief, Defendants plan and intend to, and will, actively induce infringement of the '828 patent when NDA No. 208744 is approved, and plan and intend to, and will, do so after approval.

72. Upon information and belief, Defendants know that its NDA Product and its proposed labeling are especially made or adapted for use in infringing the '828 patent, and that its NDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Defendants plan and intend to, and will, contribute to infringement of the '828 patent after approval of NDA No. 208744.

73. Upon information and belief, after approval of NDA No. 208744, Defendants will, without authority, import into the United States and/or offer to sell, sell, and/or use within the United States, a product which is made by a process that infringes one or more claims of the '828 patent prior to the expiration of the patent.

74. The foregoing actions by Defendants constitute and/or will constitute infringement of the '828 patent, active inducement of infringement of the '828 patent, and contribution to the infringement by others of the '828 patent.

75. Upon information and belief, Defendants acted without a reasonable basis for believing that it would not be liable for infringing the '828 patent, actively inducing infringement of the '828 patent, and contributing to the infringement by others of the '828 patent.

76. Unless Defendants are enjoined from infringing the ’828 patent, actively inducing infringement of the ’828 patent, and contributing to the infringement by others of the ’828 patent, Pfizer will suffer irreparable injury. Pfizer has no adequate remedy at law.

COUNT V – DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,372,995

77. Pfizer incorporates each of the preceding paragraphs 1–76 as if fully set forth herein.

78. Defendants have knowledge of the ’995 patent.

79. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Defendants’ NDA Product would infringe one or more claims of the ’995 patent, either literally or under the doctrine of equivalents.

80. Upon information and belief, Defendants will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Defendants’ NDA Product with its proposed labeling after approval of NDA No. 208744.

81. Upon information and belief, the use of Defendants’ NDA Product in accordance with and as directed by Defendants’ proposed labeling for that product would infringe one or more claims of the ’995 patent.

82. Upon information and belief, Defendants plan and intend to, and will, actively induce infringement of the ’995 patent when NDA No. 208744 is approved, and plan and intend to, and will, do so after approval.

83. Upon information and belief, Defendants know that its NDA Product and its proposed labeling are especially made or adapted for use in infringing the ’995 patent, and that its NDA Product and its proposed labeling are not suitable for substantial noninfringing use.

Upon information and belief, Defendants plan and intend to, and will, contribute to infringement of the ’995 patent after approval of NDA No. 208744.

84. Upon information and belief, after approval of NDA No. 208744, Defendants will, without authority, import into the United States and/or offer to sell, sell, and/or use within the United States, a product which is made by a process that infringes one or more claims of the ’995 patent prior to the expiration of the patent.

85. The foregoing actions by Defendants constitute and/or will constitute infringement of the ’995 patent, active inducement of infringement of the ’995 patent, and contribution to the infringement by others of the ’995 patent.

86. Upon information and belief, Defendants acted without a reasonable basis for believing that it would not be liable for infringing the ’995 patent, actively inducing infringement of the ’995 patent, and contributing to the infringement by others of the ’995 patent.

87. Unless Defendants are enjoined from infringing the ’995 patent, actively inducing infringement of the ’995 patent, and contributing to the infringement by others of the ’995 patent, Pfizer will suffer irreparable injury. Pfizer has no adequate remedy at law.

COUNT VI – DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,975,242

88. Pfizer incorporates each of the preceding paragraphs 1–87 as if fully set forth herein.

89. Defendants have knowledge of the ’242 patent.

90. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Defendants’ NDA Product would infringe one or more claims of the ’242 patent, either literally or under the doctrine of equivalents.

91. Upon information and belief, Defendants will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Defendants' NDA Product with its proposed labeling after approval of NDA No. 208744.

92. Upon information and belief, the use of Defendants' NDA Product in accordance with and as directed by Defendants' proposed labeling for that product would infringe one or more claims of the '242 patent.

93. Upon information and belief, Defendants plan and intend to, and will, actively induce infringement of the '242 patent when NDA No. 208744 is approved, and plan and intend to, and will, do so after approval.

94. Upon information and belief, Defendants know that its NDA Product and its proposed labeling are especially made or adapted for use in infringing the '242 patent, and that its NDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Defendants plan and intend to, and will, contribute to infringement of the '242 patent after approval of NDA No. 208744.

95. Upon information and belief, after approval of NDA No. 208744, Defendants will, without authority, import into the United States and/or offer to sell, sell, and/or use within the United States, a product which is made by a process that infringes one or more claims of the '242 patent prior to the expiration of the patent.

96. The foregoing actions by Defendants constitute and/or will constitute infringement of the '242 patent, active inducement of infringement of the '242 patent, and contribution to the infringement by others of the '242 patent.

97. Upon information and belief, Defendants acted without a reasonable basis for believing that it would not be liable for infringing the ’242 patent, actively inducing infringement of the ’242 patent, and contributing to the infringement by others of the ’242 patent.

98. Unless Defendants are enjoined from infringing the ’242 patent, actively inducing infringement of the ’242 patent, and contributing to the infringement by others of the ’242 patent, Pfizer will suffer irreparable injury. Pfizer has no adequate remedy at law.

WHEREFORE, Pfizer requests the following relief:

(a) A judgment that Defendants have infringed the ’828 patent, the ’995 patent, and the ’242 patent;

(b) A judgment ordering that the effective date of any FDA approval for Defendants to make, use, offer for sale, sell, market, distribute, or import Defendants’ NDA Product, or any product or compound the making, using, offering for sale, sale, marketing, distributing, or importation of which infringes the ’828 patent, the ’995 patent, or the ’242 patent be not earlier than the expiration date of the ’828 patent, the ’995 patent, or the ’242 patent respectively, inclusive of any extension(s) and additional period(s) of exclusivity;

(c) A preliminary and permanent injunction enjoining Defendants, their officers, agents, servants, employees and attorneys, and all persons acting in concert with them, from making, using, selling, offering for sale, marketing, distributing, or importing Defendants’ NDA Product, or any product or compound the making, using, offering for sale, sale, marketing, distributing, or importation of which infringes the ’828 patent, the ’995 patent, or the ’242 patent, or the inducement of or the contribution to any of the foregoing, prior to the expiration date of the ’828 patent, the ’995 patent, or the ’242 patent, respectively, inclusive of any extension(s) and additional period(s) of exclusivity;

(d) A judgment declaring that making, using, selling, offering for sale, marketing, distributing, or importing Defendants' NDA Product, or any product or compound the making, using, offering for sale, sale, marketing, distributing, or importation of which infringes the '828 patent, the '995 patent, or the '242 patent prior to the expiration date of the '828 patent, the '995 patent, or the '242 patent respectively, will infringe, actively induce infringement of, and/or contribute to the infringement by others of the '828 patent, the '995 patent, or the '242 patent;

(e) A declaration that this is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;

(f) An award of Pfizer's costs and expenses in this action; and

(g) Such further and other relief as this Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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